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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/936,565	02/04/2002	John J. Sauk	UNIMD 4	7145

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EXAMINER	
YAEN, CHRISTOPHER H	
ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 09/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/936,565	SAUK, JOHN J.	
	Examiner	Art Unit	
	Christopher H Yaen	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 February 2002*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-32* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

RE: Sauk JJ

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-9, and 11, drawn to a method of treating a patient suffering from carcinoma comprising the administration of a targeting moiety which binds to an external domain of HSP47, wherein the targeting moiety is a peptide of SEQ ID No: 1.

Group II, claim(s) 1-9, and 11, drawn to a method of treating a patient suffering from carcinoma comprising the administration of a targeting moiety which binds to an external domain of HSP47, wherein the targeting moiety is a peptide of SEQ ID No: 2.

Group III, claim(s) 1-9, and 11, drawn to a method of treating a patient suffering from carcinoma comprising the administration of a targeting moiety which binds to an external domain of HSP47, wherein the targeting moiety is a peptide of SEQ ID No: 3.

Group IV, claim(s) 1-9, and 11, drawn to a method of treating a patient suffering from carcinoma comprising the administration of a targeting moiety which binds to an external domain of HSP47, wherein the targeting moiety is a peptide of SEQ ID No: 4.

Group V, claim(s) 1-9, and 11, drawn to a method of treating a patient suffering from carcinoma comprising the administration of a targeting moiety which binds to an external domain of HSP47, wherein the targeting moiety is a peptide of SEQ ID No: 5.

Group VI, claim(s) 1-9, and 11, drawn to a method of treating a patient suffering from carcinoma comprising the administration of a targeting moiety which binds to an external domain of HSP47, wherein the targeting moiety is a peptide of SEQ ID No: 6.

Group VII, claim(s) 1-9, and 11, drawn to a method of treating a patient suffering from carcinoma comprising the administration of a targeting moiety which binds to an external domain of HSP47, wherein the targeting moiety is a peptide of SEQ ID No: 7.

Group VIII, claim(s) 1-9, and 11, drawn to a method of treating a patient suffering from carcinoma comprising the administration of a targeting moiety which binds to an external domain of HSP47, wherein the targeting moiety is a peptide of SEQ ID No: 8.

Group IX, claim(s) 1-9, and 11, drawn to a method of treating a patient suffering from carcinoma comprising the administration of a targeting moiety which binds to an external domain of HSP47, wherein the targeting moiety is a peptide of SEQ ID No: 9.

Group X, claim(s) 1-9, and 11, drawn to a method of treating a patient suffering from carcinoma comprising the administration of a targeting moiety which binds to an external domain of HSP47, wherein the targeting moiety is a peptide of SEQ ID No: 10.

Group XI, claim(s) 1-9, and 11, drawn to a method of treating a patient suffering from carcinoma comprising the administration of a targeting moiety which binds to an external domain of HSP47, wherein the targeting moiety is a peptide of SEQ ID No: 11.

Group XII, claim(s) 1-9, and 11, drawn to a method of treating a patient suffering from carcinoma comprising the administration of a targeting moiety which binds to an external domain of HSP47, wherein the targeting moiety is a peptide of SEQ ID No: 12.

Group XIII, claim(s) 1-9, and 11, drawn to a method of treating a patient suffering from carcinoma comprising the administration of a targeting moiety which binds to an external domain of HSP47, wherein the targeting moiety is a peptide of SEQ ID No: 13.

Group XIV, claim(s) 1-9, and 11, drawn to a method of treating a patient suffering from carcinoma comprising the administration of a targeting moiety which binds to an external domain of HSP47, wherein the targeting moiety is a peptide of SEQ ID No: 14.

Group XV, claim(s) 1-9 and 11, drawn to a method of treating a patient suffering from carcinoma comprising the administration of a targeting moiety which binds to an external domain of HSP47, wherein the targeting moiety is a peptide of SEQ ID No: 15.

Group XVI, claim(s) 1-9, and 11, drawn to a method of treating a patient suffering from carcinoma comprising the administration of a targeting moiety which binds to an external domain of HSP47, wherein the targeting moiety is a peptide of SEQ ID No: 16.

Group XVII, claim(s) 1-9, and 11, drawn to a method of treating a patient suffering from carcinoma comprising the administration of a targeting moiety which binds to an external domain of HSP47, wherein the targeting moiety is a peptide of SEQ ID No: 17.

Group XVIII, claim(s) 1-9, and 11, drawn to a method of treating a patient suffering from carcinoma comprising the administration of a targeting moiety which binds to an external domain of HSP47, wherein the targeting moiety is a peptide of SEQ ID No: 18.

Group XIX, claim(s) 1-9, and 11, drawn to a method of treating a patient suffering from carcinoma comprising the administration of a targeting moiety which binds to an external domain of HSP47, wherein the targeting moiety is a peptide of SEQ ID No: 19.

Group XX, claim(s) 1-9, and 11, drawn to a method of treating a patient suffering from carcinoma comprising the administration of a targeting moiety which binds to an external domain of HSP47, wherein the targeting moiety is a peptide of SEQ ID No: 20.

Group XXI, claim(s) 1-9, and 11, drawn to a method of treating a patient suffering from carcinoma comprising the administration of a targeting moiety which binds to an external domain of HSP47, wherein the targeting moiety is a peptide of SEQ ID No: 21.

Group XXII, claim(s) 1-9, and 11, drawn to a method of treating a patient suffering from carcinoma comprising the administration of a targeting moiety which binds to an external domain of HSP47, wherein the targeting moiety is a peptide of SEQ ID No: 22.

Group XXIII, claim(s) 1-9, and 11, drawn to a method of treating a patient suffering from carcinoma comprising the administration of a targeting moiety which binds to an external domain of HSP47, wherein the targeting moiety is a peptide of SEQ ID No: 23.

Group XXIV, claim(s) 1-9, and 11, drawn to a method of treating a patient suffering from carcinoma comprising the administration of a targeting moiety which binds to an external domain of HSP47, wherein the targeting moiety is a peptide of SEQ ID No: 24.

Group XXV, claim(s) 1-9, and 11, drawn to a method of treating a patient suffering from carcinoma comprising the administration of a targeting moiety which binds to an external domain of HSP47, wherein the targeting moiety is a peptide of SEQ ID No: 25.

Group XXVI, claim(s) 10, drawn to a method of modulating a cell which expresses HSP47 on its surface comprising administering to the cell an agent comprising a targeting moiety which binds to the external domain of HSP47.

Group XXVII, claim(s) 12-14, and 16, drawn to a method of detecting a carcinoma in which HSP47 is expressed on the surface comprising contacting the carcinoma with a detectable agent comprising a targeting moiety which binds to the external domain of HSP47..

Group XXVIII, claim(s) 15, drawn to a method of detecting a cell which expresses HSP47 on its surface comprising the administration to the cell a detectable agent comprising a targeting moiety which binds to the external domain of HSP47.

Group XXIX, claim(s) 17-19, drawn to a method of screening for an agent that binds to a carcinoma in which HSP47 is expressed on the surface comprising identifying an agent comprising a targeting moiety which binds to the external domain of HSP47.

Group XXX, claim(s) 20-23, drawn to a kit comprising an agent comprising a targeting moiety which binds to the external domain of HSP47.

Group XXXI, claim(s) 24-26 and 29-32 drawn to a peptide which binds to the external domain of HSP47 comprising the sequence of SEQ ID No: 1.

Group XXXII, claim(s) 24-26 and 29-32 drawn to a peptide which binds to the external domain of HSP47 comprising the sequence of SEQ ID No: 2.

Group XXXIII, claim(s) 27, drawn to a peptide of SEQ ID No: 3.

Group XXXIV, claim(s) 27, drawn to a peptide of SEQ ID No: 4.

Group XXXV, claim(s) 27, drawn to a peptide of SEQ ID No: 5.

Group XXXVI, claim(s) 27, drawn to a peptide of SEQ ID No: 6.

Group XXXVII, claim(s) 27, drawn to a peptide of SEQ ID No: 7.

Group XXXVIII, claim(s) 27, drawn to a peptide of SEQ ID No: 8.

Group XXXIX, claim(s) 27, drawn to a peptide of SEQ ID No: 9.

Group XL, claim(s) 27, drawn to a peptide of SEQ ID No: 10.

Group XLI, claim(s) 27, drawn to a peptide of SEQ ID No: 11.

Group XLII, claim(s) 27, drawn to a peptide of SEQ ID No: 12.

Group XLIII, claim(s) 27, drawn to a peptide of SEQ ID No: 13.

Group XLIV, claim(s) 28, drawn to a peptide of SEQ ID No: 14.

Group XLV, claim(s) 28, drawn to a peptide of SEQ ID No: 15.

Group XLVI, claim(s) 28, drawn to a peptide of SEQ ID No: 16.

Group XLVII, claim(s) 28, drawn to a peptide of SEQ ID No: 17.

Group XLVIII, claim(s) 28, drawn to a peptide of SEQ ID No: 18.

Group XLIX, claim(s) 28, drawn to a peptide of SEQ ID No: 19.

Group XLX, claim(s) 28, drawn to a peptide of SEQ ID No: 20.

Group L, claim(s) 28, drawn to a peptide of SEQ ID No: 21.

Group LI, claim(s) 28, drawn to a peptide of SEQ ID No: 22.

Group LII, claim(s) 28, drawn to a peptide of SEQ ID No: 23.

Group LIII, claim(s) 28, drawn to a peptide of SEQ ID No: 24.

Group LIV, claim(s) 28, drawn to a peptide of SEQ ID No: 25.

2. The inventions listed as Groups I-LIV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The technical feature linking groups I-LIV appears to be a method of administration of a targeting moiety which binds to an external domain of HSP47. However, for the purposes of this requirement, the invention of group I is interpreted as a single step of administration of a targeting moiety which binds to an external domain of HSP47. Desjardins L (US Patent 5,972,622) teaches a method of administering a targeting moiety that specifically binds to GP46 (see col. 6, lines 40-50), which Desjardins L describes as being interchangeable with the terms HSP47, HSP46, and collingins (see col. 4, lines 45-46)

3. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

a) Therapeutic Moieties: toxin, radioisotope/radionuclide, antibody, or nucleic acid;

b) Modulation of tumor cell interaction with: intracellular matrix, tumor cell invasion, migration/motility, or tumor cell metastasis

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims

subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

4. The claims are deemed to correspond to the species listed above in the following manner:

5. Claims 7 (therapeutic moieties) and claim 9 (modulation tumor cell interaction)

The following claim(s) are generic: 7 and 9.

6. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: because the technical feature so linking the claims do not correspond to a contribution over the art, the species of therapeutic moiety and modulation of tumor cell interaction also lack a contribution over the prior art.

7. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher H Yaen whose telephone number is 571-272-0838. The examiner can normally be reached on Monday-Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Christopher Yaen
Art Unit 1642
September 7, 2004

GARY NICKOL
PRIMARY EXAMINER